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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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| IN RE: Bard IVC Filters Products Liability Litigation, | No. 2:15-MD-02641-DGC<br><br>**PLAINTIFFS' BRIEF ON FOREIGN REGULATORY MATERIALS** |

In accordance with the Court's instruction at the August 23, 2015 Case Management Conference ("CMC"), Plaintiffs provide this brief in support of their request for discovery regarding foreign regulatory materials. Following the CMC, Bard confirmed that it has produced all Indications for Use ("IFUs") and that all sales and marketing materials used by foreign subsidiaries are contained in the shared drives at BPV that are to be searched and produced as part of its ESI production. Thus, the only issue is the production by Bard of foreign regulatory communications regarding IVC filters from the C.R. Bard foreign subsidiaries.

## I. Bard's Statements about Safety and Effectiveness of Its IVC Filters Are Relevant to this MDL Regarding their Safety and Effectiveness.

Bard's first objection to the production of these materials is that they are allegedly not relevant because there are no cases in this MDL for injuries from filters sold outside the U.S. But, the claims in this MDL all relate to the safety and efficacy of Bard's IVC filters and Bard's warnings regarding those filters. And, Bard's statements and communications with foreign regulators regarding the safety and effectiveness of those filters is relevant to those very issues.

Advocating the relevance of regulatory communications, Bard has produced its communications with the FDA relating to IVC filters as well as communications between its U.S. employees and foreign regulatory agencies about those filters. The only issue appears to be the communications by its non-U.S. employees (or those U.S. employees responsible for foreign interactions) who interact with the foreign regulators. But, those communications are no less relevant, as they go to the same issues.

Additionally, foreign regulatory documents from outside the MDL demonstrate how communications with foreign regulators are relevant to the issues here. For example, in January 2014, the MHRA (England's equivalent to the FDA) issued a guidance for reporting IVC filter complications, listing various complications that can occur and essentially what to look for with these devices. [Ex. 1.] This report (and similar communications from foreign regulatory agencies) go to notice – if Bard received similar

earlier communications from the MHRA, they would be highly relevant to its notice and, thus, the failure-to-warn claims. Similarly, foreign recall issues (such as the February 2016 Denali recall in Canada, [Ex. 2]) gave Bard information regarding filter defects and Plaintiffs grounds to advocate that similar actions should have been taken by Bard in the United States.

## II. Bard's "International" Companies Create Some of Their Own Regulatory Materials.

In objecting to Plaintiffs' request for foreign materials, Bard relied on the testimony of Robert Carr. Mr. Carr was Bard's designated witness for the Rule 30(b)(6) deposition on organizational structure, a deposition that covered four topics: (1) the current and historical corporate divisions of CR Bard; (2) the current and historical subsidiaries of CR Bard; (3) the business in which each of those divisions and/or subsidiaries engaged; and (4) whether each division or subsidiary had or has anything to with IVC filters (and, if so, what)? Significantly, Mr. Carr was not designated as the corporate representative on either the overall structure of Bard's information systems or as to the locations of ESI specific to IVC filters. That witness was Christopher Adickes who was interviewed and deposed separately from Mr. Carr.[1]

In terms of corporate structure, Mr. Carr testified that Bard's foreign (non-U.S.) subsidiaries that fall under its "international" division "are all commercial sales structures in those regions and/or countries -- … that sell all Bard products or whatever products they sell in that country." Rule 30(b)(6) deposition transcript of Robert Carr, Ex. 3, at 45:25-46:7. He further testified that these entities "liaison[] with the [foreign] regulatory branch." *Id.* at 19:22-23:7. It is clear from Mr. Carr's testimony and the documents produced to date that, in their role of liaising with foreign regulatory bodies, those foreign subsidiaries can make changes to important documents, including the IFUs, based on regulatory issues and communicate directly with foreign regulators regarding safety and

[1] Significantly, on issues as to regulatory documents relating to IVC filters, Mr. Adickes testified that he did not know what information exists or where it is located.

efficacy issues. On that point, Mr. Carr testified that "if [an IFU] happens to have a different indication for use in a different country, … they [the foreign subsidiary] would be able to change that information." *Id.* at 57:19-58:4. He further testified that changes to IFUs are not approved domestically but are approved at the foreign subsidiaries themselves. *Id.* at 58:5-8.

Indeed, Bard has produced documents demonstrating conclusively that its foreign subsidiaries deal directly with foreign regulatory agencies on regulatory issues in those countries, including safety and efficacy. For example, in March 2005, David Marshall, the Director of Regulatory Affairs & Quality Assurance for Bard Europe in England, consulted directly with the MHRA regarding whether "Vigilance" reporting (the equivalent to the FDA's Adverse Event Reporting) was necessary. [Ex. 4.] And, in 2007, Mr. Marshall was engaged in extensive direct communications with the MHRA regarding its safety concerns about the G2 filter. [Ex. 5.] These communications are partially documented in an email from Mr. Marshall to Gin Schulz at BPV, but they demonstrate the existence of substantive communications by Bard foreign subsidiaries with foreign regulators regarding the safety and efficacy of the very devices at issue in this MDL.

Thus, Bard foreign subsidiaries have unique regulatory documents regarding the safety and efficacy of IVC filters. Certainly, there are readily identifiable individuals at those organizations who deal with the foreign regulatory agencies and who will have emails and files containing those communications. Contrary to Bard's suggestion, this is not hunting for a "needle in a haystack" any more than it is to locate Bard's communications with the FDA regarding IVC filters.

For these reasons, Plaintiffs request that the Court order Bard to produce the foreign regulatory materials relating to IVC filters from its foreign subsidiaries.

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RESPECTFULLY SUBMITTTED this 25th day of August 2016.

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 25, 2016, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/ Gay Blakesley

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